

**MDCH Comments and Recommendations for CON Standards Scheduled for 2008 Review  
Presented to CON Commission January 24, 2008**

| <b>Surgical Services</b><br>(Please refer to the attached MDCH staff analysis for additional details.)  |  |   |  |
|---|--|---|--|
| All Identified Issues   | Issues Recommended as Requiring Review | Recommended Course of Action to Review Issues | Other/Comments   |
| 1. Should the covered service continue to be regulated?   | Not Applicable                         | Continued Regulation.                         |  |
| 2. Inclusion of an exception to the volume requirements for an FSOF with one operating room that is contiguous to a freestanding emergency room that receives ambulance traffic.  | No                                     | No action.                                    | See MDCH staff analysis on page 3.   |
| 3. Inclusion of language to clarify the process of deducting previously committed projections.  | Yes                                    | Draft recommended changes.                    | Inclusion of language would provide clarification on the established process within the Standards. |
| 4. Department recommended technical changes.  | Yes                                    | Draft recommended changes.                    | Technical changes to the Standards to ensure uniformity within all CON Standards.                  |
| <b>Recommendation: The Department recommends that the Commission assign the responsibility to draft the necessary changes for 3 and 4 to Department staff. The Department shall present the draft language to the Commission for proposed action at its March 11, 2008 meeting.</b> |  |   |  |

## **MDCH Staff Analysis of the Surgical Services Standards**

Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to “..review, and if necessary, revise each set of CON standards at least every 3 years.” In accordance with the established review schedule on the Commission Workplan, the Surgical Services Standards are scheduled for review in calendar year 2008.

### **Public Hearing Testimony**

The Department held a Public Hearing to receive testimony regarding the Standards on October 31, 2007, with written testimony being received for an additional 7 days after the hearing. Testimony was received from three organizations and is summarized as follows:

1. The Michigan Health Ministries of Ascension Health
  - Supports continued review of the standards on a three-year schedule.
2. Spectrum Health Hospitals
  - Supports current standards with no modifications.
3. William Beaumont Hospitals
  - Supports continued regulation of surgical services.
  - Recommends language to clarify the process of deducting previously committed projections.
  - Recommends an exception from the volume requirement for a Freestanding Outpatient Surgery Facility (FSOF) with one operating room that is contiguous to a freestanding emergency room.

### **Regulation of Covered Service**

Michigan is one of 22 states which regulate surgical services within CON. The Department received testimony from two organizations which support the continued regulation of surgical services. The Surgical Services Standards require that operating rooms are exceeding volume levels prior to the initiation of a new service or expansion of an existing service. Thus, the regulation of Surgical Services ensures appropriate utilization of each operating room to keep Michigan right-sized.

### **Documentation of Projections**

The Department received a request to include language which outlines the process for documenting projections under Section 11 of the Standards. This would offer additional clarification to the Standards on the established administrative practice. The change would be technical in nature and Section 11(1) would be modified to read as follows:

Section 11(1) An applicant required to project volumes of service shall specify how the projections were developed and shall include only surgical cases performed in an OR.

- (a) The applicant shall include a description of the data source(s) used as well as an assessment of the accuracy of these data used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.
- (b) The Department shall subtract any previous projections, pursuant to subsection 2(d).

### **Volume Exception**

The Department received a request to include an exception to the volume requirements for an FSOF with one operating room that is contiguous to a freestanding emergency room that receives ambulance traffic. Ambulances are dictated by Administrative Rule 325.22112, which states:

R 325.22112(1) An ambulance operation, both ground and rotary, shall transport an emergency patient only to an organized emergency department located in and operated by a hospital licensed under part 215 of the code or to a freestanding surgical outpatient facility licensed under part 208 of the code that operates a service for treating emergency patients 24 hours a day, 7 days a week and complies with medical control authority protocols.

Pursuant to MCL 333.22205, a hospital licensed under part 215 and an FSOF licensed under part 208 are both classified as a health facility. A freestanding emergency room is not a health facility, but by having an FSOF, the freestanding emergency room becomes a health facility. With appropriate protocols, it can receive ambulance traffic.

The Surgical Services Standards require an applicant applying for a FSOF to provide projections from physicians, who commit to perform their cases at this proposed facility for three years. The standard ensures that the operating room will be able to meet the volume requirements. The exception would provide a non-health facility the ability to become a health facility and side step the standard of using historical cases to initiate a new service.

### **Technical Changes**

The Department is recommending that an exception to the requirements for relocation of an existing service with one or two operating rooms, which is located in a rural or micropolitan statistical area county. This exception would be identical to the exception found in Section 6(3) of the Standards. The inclusion of this exception would give uniformity for replacing and relocating an existing service within the Standards.

### **MDCH Staff Recommendations:**

- Continued regulation of surgical services to ensure that there is not a proliferation of this service within Michigan.
- Continued volume requirement for all operating rooms.
- Draft changes to the Standards to include the clarifying language under Documentation of Projections and the technical changes for presentation to the Commission at the March 11, 2008 meeting.